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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,036	04/02/2004	Eric R. First	17675 (BOT)	2222

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,036	FIRST, ERIC R.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14,18-20 and 22-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,18-20,22-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5, 7-14, 18-20, 22-37 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2006 has been entered.

Objections/Rejections Withdrawn

1. The rejection of claims 1-2,4-7, 11-12, 14, 16 under 35 U.S.C. 102(e) as being anticipated by Pastan et al (US PG-Pub 2004/0087772 A1) is traversed on the grounds that: "the Pastan reference is herein withdrawn in light of the amendment of the claims to be directed to the treatment of non-cancerous melanin related affliction.
2. ***Claim Objections*** Claim 7 objected to because of the following informalities: Claim 7 should depend from a prior claim (lower number) and not from a later presented claim; Claim 7 depends from claim 16 which is a later presented claim. Appropriate correction is required.
Claim Rejections - 35 USC § 112 Claims 2-4, 8-10,15- 16, 18-21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been obviated by amendment of the claims, or cancellation of claims.
3. ***Double Patenting*** Claim 1 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 22 is herein withdrawn in light of the
4. Claims 1 and 22 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40 and 45 of copending Application No. 10/929,040 is herein withdrawn in light of the claims having been amended to recite "non-cancerous melanin related affliction" and the copending application claims are directed to treating cancerous melanoma.
5. Claims 1-5,8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Waugh et al (US PG-Pub 2004/0220100 A1, filing date March 3, 2004), in light of the fact that the pigmented cells of Waugh et al are melanoma cells.

Response to Arguments

6. Applicant's arguments filed October 27, 2006 have been fully considered but they are not persuasive.

7. ***Maintained Rejection Claim Rejections - 35 USC § 102:*** The rejection of Claims 1, 3-4, 11-14, and new claims, 18, 20 under 35 U.S.C. 102(b) as being anticipated by M. Rodriguez Vazquez et al (2002) is traversed on the grounds that:

8. Vazquez does not disclose nor treat a melanin related affliction.

9. It is the position of the examiner that Vasquez et al does disclose the instantly claimed method, the method comprising the step of administering botulinum toxin serotype A to a patient with a skin region exhibiting a symptom of a melanin related affliction, the symptom being vascularization (see Vazquez, page 155, col. 1, paragraph 4 "associated with vascular proliferation"), as well as a hyper-pigmented area (see page 154, col. 1, paragraph 4) of patient skin (see page 154, "Case Report) to alleviate the melanin related affliction symptom.

10. When the first treatment did not work, the patient was in need of a treatment that would work to reduce general pain, associated with the hyper-pigmentation region that comprised hair. The pain was associated with ductal hyperplasia and dilated coils without epidermal changes (see Figure 2).

11. The patient treated by Vasquez et al was identified as a patient with a melanin related affliction, which was not successfully treated by another conventional method of treatment, but was successfully treated with botulinum toxin when the botulinum toxin was administered to the location of skin that comprised hair and hyperpigmentation. The melanin related affliction was

treated by administration of botulinum toxin, in light of Vazquez et al disclosing a 50% reduction in sweating, due to administration of botulinum toxin (see summary at end of article).

New Grounds of Objection/Rejection
Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 8-10, recites the limitation "a change" in reference to the preamble which does not provide antecedent basis for these limitations. There is insufficient antecedent basis for this limitation in the claim.

14. Claims 2, 8-10, 19, 23-24, 31-32 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the critical claim limitations that distinguish the ability of botulinum toxin to both increase and decrease color pigmentation in hair or skin. The essential elements are missing from the claims. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. Roehm et al (1999) teaches botulinum toxin to decrease pigmentation or not to change pigmentation at all depending on the patient population, no patients increased pigmentation. Clarification of the claims to recite the critical distinguishing characteristics is requested. See In re Mayhew

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1, 3-5, 7, 11-14, 18 , 20, 22, 24 -30, 32-37,are rejected under 35 U.S.C. 102(b) as being anticipated by Binder (US Pat. 5,670,484).

Binder disclose the instantly claimed invention directed to a method of treating a non-cancerous melanin related affliction in a patient, the method comprising the step of:

Instant claim 1, 4-5, 18: Administering botulinum toxin to the skin of the patient exhibiting the symptom, wherein the patient any one or more of atopic or seborrheic determatitis (an inflammatory condition that presents with white to yellowish scales and includes the affliction of cradle cape which presents with yellow or brown lesions), psoriatic lesion (col. 1; col. 5, lines 12-27), or other cutaneous cell-proliferative disorders (col. 3, lines 25-35); wherein the administration alleviates at least one symptom of the affliction (see col. 6, lines 34-37 "controlling symptoms associated with the disorder" and "inducing remission of the disorder" by "eliminating existing lesions").

Instant claim 3, 20, 24, 32: wherein the affliction is associated with increased pigmentation "controlling symptoms associated with the disorder", "inducing remission of the disorder" "eliminating existing lesions". (col. 6, lines 34-37).

Instant claim 7: wherein the botulinum toxin is a native botulinum toxin (see col. 3, lines 57-67 and col. 4, lines 1-45).

Instant claim 11-12, 25-26, 33-34: wherein the botulinum toxin is serotypeA, B, C, D, E, F or G (see col. 3, lines 62, and col. 4, line 2 and col. 2, line 45).

Instant claim 13, 27, 35: wherein the dose administered is between 1unit and 3,000 units (see col. 5, lines 37-50 "5-15 units"; and examples and up to 1000 units).

Instant claim 14, 29, 37: wherein the administering is subcutaneous (see col. 3, lines 55 "subcutaneous layers of cells"; col. 6, lines 10-12).

Instant claim 29, 37: wherein the administering is topical (see col. 4, lines 62 "topical administration "). The reference anticipates the instantly claimed invention as now claimed

Please Note: the following prior art rejection is being made of record as the amended claims are directed to alleviating a symptom associated with a non-cancerous melanin related affliction.

17. Claims 1, 4, 11, 13, are rejected under 35 U.S.C. 102(b) as being anticipated by Borodic (US Pat. 6,429,189, issue date August 6, 2002).

Borodic disclose the instantly claimed invention directed to a method, the method comprising the step of:

Administering 5-20 Units of botulinum toxin to the skin exhibiting a symptom of a melanin related affliction, the symptom being edema, redness, (see Borodic, claim s 18-19),

inflammation, pain and vascularization (see Borodic, claim 5, 19, 20 "cystitis", claim 24 "inflammation or pain caused by vasculitits"), wherein the botulinum toxin is type C (see Borodic, claim 8). The reference anticipates the instantly claimed invention as now claimed

18. Claims 1, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Coe et al (PG-Pub 2001/0036943).

Coe et al disclose the instantly claimed invention directed to a method that reduces a symptom associated with an affliction, the affliction being a keloid (scar pain, see Coe claims 33-34), the method comprising the step of:

Administering botulinum toxin (see Coe et al, page 13, claim 2, last line and page 16, claim 17-18) to reduce the symptom of pain.

Coe et al anticipates the instantly claimed invention as now claimed.

19. Claims 1, 3,4,5,7, 11-12, 14, 18, 20, 22, 24, 25-26, 29, 32-34, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Zeldis et al (PG-Pub 2005/0214328, effective filing date March 22, 2004).

20. Zeldis et al disclose the instantly claimed invention directed to a method being on that treats a non-cancerous melanin related affliction, the affliction being a keratosis skin disorder (see claims 1,5,6,19,20, and abstract), the method comprising the step of:

Administering (see [0294 "topically"," subcutaneously"]) botulinum toxin (see Zeldis claims 1 and 5, 6) to the skin (skin diseases) or hair follicle (see [0010] Keratoacanthoma0 of the patient

(see abstract "skin diseases or disorders" and [0005-11] [0010 "hair follicle"}; [0073 cutaneous vasculitis]; [0093-0104]) to alleviate at least one symptom (see [0287 "averting of symptoms associated with skin diseases, conditions or disorders to include inflammatory responses (see bottom of [0287]; [0297 "BOTOX", "botulinum toxin"). The reference anticipates the instantly claimed invention as now claimed

Double Patenting

21. Claim 1, 22, 5, 25-26, 27-28 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 46 of copending Application No. 10/929,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention is directed to a genus of methods that by definition in the instant specification the claimed species recited in claim 46 of US Application 10/929,040. The copending species directed to treating a melanoma anticipates the instantly claimed genus of treating any type of melanin related affliction and is an obvious species of the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

This is a non-final action.

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 20050196414A1is cited to show the administration of botulinum toxin to alter

hair growth (claim 131).US007149574B2 is cited to show the administration of botulinum toxin to a subject. US 20040248188A1 is cited to show the administration of tetanus toxin to treatment of aged skin (see claims 1 and 63). US 20050074466A1is cited to show the administration of botulinum toxin to treat acne vulgaris. US 20050175637A1 is cited to show the administration of botulinum toxin for enhancing wound healing. US 20050239705A1 is cited to show the administration of botulinum toxin for therapeutic delivery of biologically active agents. US 20050148935A1 is cited to show a botulinum toxin injection guide. US 20050261632A1 is cited to show a microdivice for the administration of botulinum toxin to treatment of dark spots, skin discoloration, skin lightening, skin whitening, facial hair growth, acne, warts (see claims 10-20). US 20060165657A1 is cited to show methods of tanning the skin, reducing incidence of acne, diminishing the appearance of scar by administering a composition that comprises a vector encoding botulinum toxin. 20040060569 is cited to show a method of administering botulinum toxin to a skin wrinkle. US 20030113349A1 is cited to show the topical application of botulinum toxin. Medline definition of Seborrheic dermatitis is provided. US 20050123567A1 (Eric First) is cited to show botulinum toxin therapy for treatment of dermatofibroma, keloid, moles nevi, seborrheic keratose [003]).US 20030166004A1 is cited to show the treatment of keloids and pyogenic granulomas with a neurotoxin. US 20050220820A1 is cited to show the administration of botulinum toxin to control dermal cysts (see [0098, and 0051]). US Pat. 6,299893 is cited to show botulinum toxin to prevent hair loss and increased hair growth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
January 5, 2007

MARK NAVARRO
PRIMARY EXAMINER